K111858

NOV - 4 2011

510(k)Summary

SANO Transportgerate GmbH
LIKFTKAR PT™ -S, Powered Patient Transport Device
PRODUCT CODE **ILK**
Regulation Name **Powered Patient Transport 890.5150**
Class II

Submitter's Information

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Manfred Winkler
Managing Director

Dated Prepared: 08/21/11 Revised on 10.5.11

Name of Device and Sponsor
LIFTKAR PT™-S Product of SANO

Common Name
Integrated Seat Stairclimber

Classification Name
Powered Patient Transport

Predicate Device
C-Max-U2 (AAT Alber Antriebstechnik GmbH) K103122

***Intended Use**
The product is a method of transporting a disabled person up and down stairs while seated on the stairclimber and not in a wheelchair. This is done with a battery powered lifting mechanism. The LIFTKAR PT-S requires a certified attendant and can be use on any stairs indoor or outside.

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Device Description

The LIFTKAR PT™ S is an attendant operated, battery powered lifting device that transports a disabled person in an integrated chair up or down stairs, not in a wheelchair. The LIFTKAR PT-S is designed for indoor and outdoor use allowing mobility for the person needing assistance.

*Attendants are trained and certified before using the device.

The portable stair-climber LIFTKAR PT-S can be dismantled into three parts, the climber unit with integrated seat, the battery pack and the handle which includes backrest and armrest. All parts are lightweight and easy to stow away.

Product	**PT-S**
Technical Data	
***Weight** (total):*	67 lbs
Safe Workload (incl. chair	352 lbs persons wt.
Overall height:	44.49 inches
***Overall width**: (w/o armrests)*	19.88 inches
Depth (footrest out)	29.3 inches
***Stair Landing minimum:**	*31.5 x 35.4 inches (Includes landings for **all** types of stairs)*
Maximum Stair Height	8.25 inches
*Any Stair Type Depth:	6 inches (includes winding)
*Straight stair width:	23.81 inches (includes Liftkar plus 3.93 inches)
*Winding Stair Width:	23.81 inches from point of stair depth of 6 inches
Battery	Sealed lead gel
Capacity with fully charged batter	300-500 steps
Battery capacity	2x 12V 5 ah

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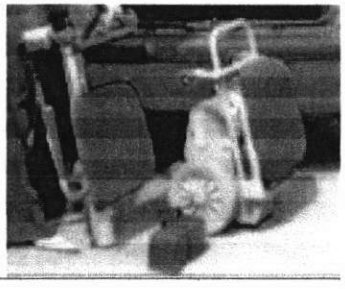
Nominal output voltage of charged 24 V

Main components:
Handle, lifting device, battery

***Climbing Speeds**
I 10 steps per minute
II 14 steps per minute
III 18 steps per minute
Continuous Mode may be used, if stairs are straight, and there is no landing. Contiuous mode is 18 steps per minute. It is recommended for professional use only.

Liftkar PT-S



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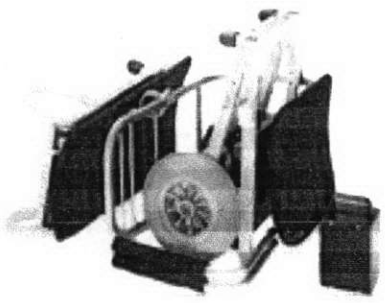
Substantial Equivalence

The LIFTKAR PT™ S is substantially equivalent in intended use, design and function to the C-Max-U2 K103122 manufactured by AAT.

C-Max



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Listed Below are the similarities or differences:

Product Comparison

	C-Max-U2	PT-S
***Weight** (total):*	78.7 lbs	67 lbs
Safe Workload (incl. chair)	352 lbs	352 lbs persons wt.
Overall height:	44.4 inches	44.49 inches
***Overall width**: (w/o armrests)*	16.9 inches	19.88 inches
Depth (footrest out)	30.9 inches	29.3 inches
Stair Landing minimum:	*31.5 x 35.4 inches*	*31.5 x 35.4 inches*
Maximum Stair Height	8.26 inches	8.25 inches
Battery	Sealed lead acid	Sealed lead gel
Capacity with fully charged battery	300 steps	300-500 steps
***Speeds**	8-23 steps/min	10-18 steps/min
	Continually adjustable	Continuos Mode
Battery capacity	2x 12V 5 ah	2x 12V 5 ah
Nominal output voltage of charge	24V	24 V
Main components: Handle, lifting device, battery	Same	Same

Performance Data

The LIFTKAR PT™-S was tested by BERLIN CERT Pruf und Zertifizierstelle for Medizinnprodukte GmbH an der Technischen Universitat Berlin, TEST Reports in Section: 11.7-32

LIFTKAR PT –S conforms with the following standards :

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ISO 7176-23:2002 Requirements and Test Methods for attendant - operated stair climbing devices

Biocompatibility DIN EN ISO 10993-5 Biological Evaluation and testing of Cytotoxicity

The performance Data results of the testing confirm that the device meets specifications for performance criteria and the functions it was intended for. And is substantially equivalent to the predicate device.

Conclusion

Based on the design, performance specifications, testing, and intended use, the LIFTKAR PT™ -S is substantially equivalent to the legally marketed device, C-Max k103122

Since the device is essentially the same as the powered patient transporter already marketed, (C-Max K103122), no effect on the safety and or effectiveness of the device is expected.

* Denotes corrections made or added relating to 9.28.11 from FDA re: K111858 Liftkar PT-S (Also underlined)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

SANO Transportgeracte GmbH
% Mobility Lifter, LLC
Ms. Jeanine A. Carroccio
4028 Belleaire Lane
Downers Grove, Illinois 60515

NOV - 4 2011

Re: K111858
Trade/Device Name: LIFTKAR PT™-S
Regulation Number: 21 CFR 890.5150
Regulation Name: Powered patient transport
Regulatory Class: II
Product Code: ILK
Dated: September 28, 2011
Received: October 12, 2011

Dear Ms. Carroccio:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATION FOR USE

510(k) Number: K111858

Device Name: LIFTKAR PT™-S

Indications For Use:

The LIFTKAR PT™-S Is a method of transporting disabled persons, up and downstairs while seated on the stairclimber, and not in a wheelchair. This is done with a lifting mechanism. It is a battery powered lifting mechanism. LIFTKAR PT™-S requires a certified attendant and can be used on any stairs indoors or outside.

Prescription Use _____ AND/OR Over-The-Counter Use__X__

(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K111858